

DISPOSITION: 2-21-61. Consent—claimed by E. Vadillo Ruiz, Inc., New York, N.Y., and released under bond for export to the original foreign supplier, Dr. Bell Veterinary Medicine Co., Kingston, Canada.

DRUG ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

6595. Elixir of phenobarbital and belladonna. (F.D.C. No. 45301. S. No. 2-739 R.)

QUANTITY: 4 50-gal. drums at Atlanta, Ga.

SHIPPED: 10-18-60, from Greenville, S.C.

LIBELED: 12-21-60, N. Dist. Ga.

CHARGE: 501(a)—contained plant fibers, metallic particles, and whole insects while held for sale.

DISPOSITION: 2-6-61. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS FOR HUMAN USE*

6596. Ferrous sulfate tablets. (F.D.C. No. 45505. S. No. 99-459 R.)

QUANTITY: 53 100-tablet btls. at Gardiner, Maine.

SHIPPED: 11-9-60, from Worcester, Mass., by Buffington's, Inc.

LABEL IN PART: (Btl.) "Entells VIRON * * * Ferrous Sulfate Exsiccated 5 grains. Entells designates Buffington brand Enteric Coated Tablets. Dose: * * * Buffington's Inc. * * * Worcester, Mass."

LIBELED: 3-8-61, Dist. Maine.

CHARGE: 501(b)—when shipped, the article purported to be, and was represented as, *ferrous sulfate tablets*, a drug, the name of which is recognized in the United States Pharmacopeia, an official compendium, and was represented to be enteric-coated, and its quality fell below the official standard for enteric-coated tablets since the articles failed to meet the disintegration requirements for enteric-coated tablets as provided in the official compendium; and 502(a)—the label statement "Ferrous Sulfate Exsiccated 5 grains" was false and misleading as applied to the article which purported to supply 5 grains of ferrous sulfate in a form assimilable to the body but failed to do so.

DISPOSITION: 3-23-61. Default—destruction.

6597. Cecobee vitamin injectable. (F.D.C. No. 45521. S. No. 14-934 R.)

QUANTITY: 80 ctnd. vials at Cincinnati, Ohio.

SHIPPED: 1-27-61, from Philadelphia, Pa., by Philadelphia Ampoule Laboratories, Inc.

LABEL IN PART: (Bulk ctn.) "20 cc. No. 1109 Multiple Dose Vial B₁₂ Plex C A Stable B Complex with B-12 and C Caution: * * * Phila. Ampoule Laboratories Philadelphia 23, Pa. * * * Each cc. contains: * * * Thiamine HCl 50 mg."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 70 percent of the declared amount of vitamin B₁₂.

The article was shipped in bulk cartons of 50 unlabeled vials each and after receipt by the dealer, each vial was labeled and packed in individual cartons.

*See also No. 6593.

LIBELED: 3-15-61, S. Dist. Ohio.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it was purported to possess; and 502(a)—the label statement "Thiamine HCl. 50 mg." was false and misleading.

DISPOSITION: 4-14-61. Default—destruction.

6598. Vitamin B complex with B₁₂. (F.D.C. No. 45109. S. No. 32-352 R.)

QUANTITY: 518 cartoned vials at Brooklyn, N.Y.

SHIPPED: 8-25-60 and 8-26-60, from Philadelphia, Pa.

RESULTS OF INVESTIGATION: Examination showed that the article contained approximately 17 percent of the declared amount of vitamin B₁₂.

LIBELED: 12-5-60, E. Dist. N.Y.

CHARGE: 501(c)—while held for sale, the strength of the article differed from, and its quality fell below, that which it purported or was represented to possess; and 502(a)—the label statement "Each cc. contains vitamin B-12 30 mcgms." was false and misleading.

DISPOSITION: 3-3-61. Default—destruction.

6599. Hemacombin-P tablets. (F.D.C. No. 45148. S. No. 8-731 R.)

QUANTITY: 2 drums, containing a total of 24,500 tablets, and 5 100-tablet btl., at Rensselaer, N.Y.

SHIPPED: 3-1-60, from Englewood, N.J.

RESULTS OF INVESTIGATION: The article in the bottles had been repacked from bulk stock which had been shipped as described above. Analysis showed that the article contained approximately 73 percent of the declared amount of dextro-amphetamine sulfate.

LIBELED: 11-18-60, N. Dist. N.Y.

CHARGE: 501(c)—while held for sale, the strength of the article differed from, and its quality fell below, that which it purported and was represented to possess; and 502(a)—the label statement "Dextro Amphetamine Sulfate 1.5 mg." was false and misleading.

DISPOSITION: 3-22-61. Default—destruction.

6600. Clinical thermometers. (F.D.C. No. 45414. S. No. 27-398 R.)

QUANTITY: 37 boxes of 12 thermometers mounted on cardboard carriers with 6 thermometers on each carrier, and 2 carriers in each box, at Minneapolis, Minn.

SHIPPED: 12-20-60, from New York, N.Y., by Chase Bottle & Supply Co.

LABEL IN PART: (On thermometer) "Serial Number * * * C. F. Anderson * * * Oral."

RESULTS OF INVESTIGATION: Examination of 24 thermometers showed that 3 failed to meet the requirements for accuracy specified in CS1-52, issued by the National Bureau of Standards of the Department of Commerce, when tested as described in CS1-52; 1 failed to meet the requirement for retreating index as specified in CS1-52; 2 failed to meet the requirements for construction as specified in CS1-52; and 4 had the minor construction defect of having triplicate serial numbers.

LIBELED: 2-9-61, Dist. Minn.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported and was represented to possess; and 502(a)—the labeling